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GB05/1238



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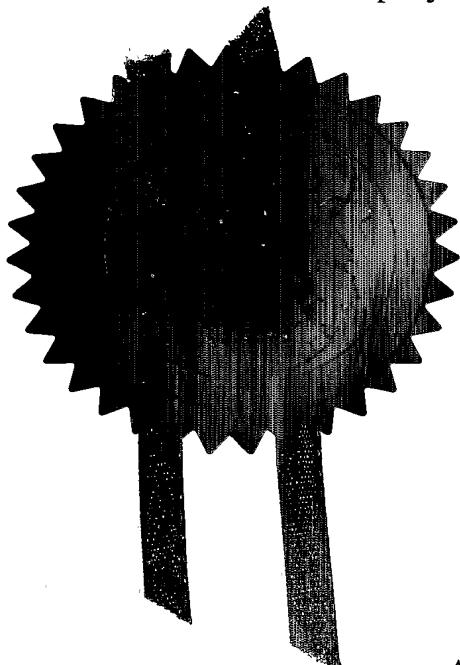
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3. Full name, address and postcode of the or of each applicant (underline all surnames)

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Patents ADP number (if you know it)

8841371001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

URINARY INCONTINENCE DEVICE

5. Name of your agent (if you have one)

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Description	6
Claim(s)	3
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URINARY INCONTINENCE DEVICE

The present invention relates to a female incontinence device, in particular an external incontinence device.

Due to the anatomy of the female external urogenital organs, the management of incontinence in female patients has always been difficult both in terms of preventing leakage and acceptability for the patient. There have been a number of devices for female incontinence that attempt to secure an effective seal in a number of ways.

Some devices provide an intra vaginal structure to support the device in place.

Examples of such devices include those described in US patent 3776235 (Ratcliffe et al), US 3661155 (Linden), US 4198979 (Cooney et al), US 4019498 (Hawtrey et al), US 5785640 (Keresch et al) and UK patent applications GB 2126902A and GB 2090144A. However, such devices have been found to be rigid, uncomfortable, intrusive and still prone to leakage.

Other devices have used an external adhesive in an attempt to seal the device to the patients skin and avoid leakage. Examples of such devices include US patent 4822347 (MacDougal) and UK applications GB 2129686A and GB 2193438A. These devices have also proven to be ineffective in providing an effective seal, particularly with mobile patients.

Further devices include US 4846819 (Welch) which employs a deformable polymer gel ring to provide a seal. The use of a sealing pad of foam plastic material is described in US patent 3374790 (Mayhorne) but again these devices have been found to be ineffective in preventing leakage.

There remains a need for a female incontinence device that can provide an effective seal for both mobile and immobile patients whilst remaining comfortable for the patient. The present invention overcomes these problems by providing a device that utilises a flexible strip to form a seal about the female external urogenital organs. accordingly the present invention provides A female urinary incontinence device comprising a flexible elastic strip having an upper face and a lower face, an opening being provided in the strip communicating between the upper and lower faces, a fluid collection means affixed to the strip in a fluid tight manner around the opening and further comprising an outlet for conveying fluid away from the collection means, wherein the strip and opening are sized and shaped such that when it is stretch fitted over the external urogenital organs the labia minor extends through the opening and a fluid tight fit between the upper face of the strip and the labia majora and the base of the labia minora is formed, such that in use urine is conveyed from the urethra, through the labia minora, and into the collection means without leakage.

The flexible strip may be constructed of any suitable material having a degree of elasticity and flexibility to maintain a fluid seal during use. Suitable materials include elastomeric materials such as silicon or latex rubbers. Preferably, the material is hypoallergenic.

The opening in the strip is preferably of a substantially oval shape to assist in maintaining a seal about the labia minora. The strip in the region of the opening may also have a substantially oval shape.

The device further comprises a fluid collection means which surrounds the opening on the lower face of the strip in a fluid tight manner. Preferably, at least the portion of the collection means immediately adjacent the lower face is comprised of the same material as the strip. The collection device, or the portion adjacent the lower face and surrounding the opening, can be affixed to the lower face of the device by for example heat welding or by an adhesive but preferably it is formed integrally with the strip. In a preferred embodiment, the collection device comprises an oval cup portion surrounding the opening and formed integrally with the strip and of the same material. A second portion of the cup is separated by a thin resilient inner wall also having an opening therein and separating the first portion of the cup from the second portion which comprises a hard shell narrowing to an outlet toward its lower end which may be attached to a tube for draining urine or other fluid discharge to a storage vessel for subsequent disposal. The interior wall prevents or reduces backflow of discharged fluid, particularly if the user is in a lying position.

The device may be in the form of integral incontinence pants. Preferably the device is in a two part form, the first part comprising the strip and collection means provided with connection means for connection to a support means. The connection means may comprise a plurality of straps that can be connected to straps or tensioning means attached to a waistband. Preferably the connection means between the strap portion and the connections on the support means can be adjusted to maintain a positive tension so as provide a force urging the inner face of the strap against the labia majora which helps to maintain a fluid tight seal. The strap portion can for example be connected to the support means by a number of elastic straps.

Preferably the strap portion can be disconnected from the support means so that another strap portion can be fitted. The strap portion can then be sterilized for reuse which can provide a considerable cost saving over disposable devices.

The device is comfortable for long term wear and does not include any internal support structure such as a vaginal or urethral insertion to hold the device in place. The device does not rely on adhesive or contact sensitive areas such as the vaginal or urethral orifice (meatus). The device can be used for permanently immobilised patients but due to the efficient sealing provided by the flexible elastomeric material the device is also suitable for mobile patients. The device is also much easier for hospital staff to change than devices which require vaginal insertion or catheterisation and avoids the possible complications such as infection that can be associated with such procedures. The device can also be used to collect urine from uncooperative patients such as children or those suffering from dementia. The device can also be used to collect other vaginal discharge such as experienced during heavy periods and give the doctor an indication of the amount of bleeding.

The invention will now be described by way of example with reference to the accompanying drawings in which:

Figure 1 is a schematic view of a urinary incontinence device according to an embodiment of the invention.

Figure 2 is a schematic view of the device of Fig attached to a support harness.

Referring to Fig 1, there is shown a urinary incontinence device 13 which comprises a strap part 1 made of a flexible, elastic silicon rubber material, the strap part has a substantially oval central portion 2 having an oval opening 3 therein. A fluid collection part 4 comprises a first cup portion 5 which is formed integrally with the strap part surrounding the opening on the lower face. The first cup portion is about 10mm deep and spaced from the edge of the opening by about 5mm. A second cup part is joined to the first cup part. The second cup part has an exterior wall 7 which is formed from a plastics material that is sufficiently thick and rigid to maintain its oval shape in use and which narrows at its lower end to form a tubular exit 8 that can be connected to drain to an external container. An interior wall 9 comprised of a resilient and flexible material is provided toward the upper end of second the cup part and spaced from the exterior wall, having a substantially oval opening 10 therein. The strap part divides at either end to form front support arms 11 and rear support arms 12.

Referring to Fig 2, in use the patient is fitted with a support harness 17 comprising a waistband 14 having front support straps 15 and rear support straps 16 attached to the waistband. The front 11 or rear 12 support arms of the incontinence device can be attached to the corresponding front 15 or rear 16 support straps of the harness. The strip portion is then stretch fitted so that the labia minora of the patient passes through the opening in the strip portion and through the opening of the interior wall. When the strip portion is relaxed the base of the labia minora is surrounded by the opening in the strip portion. The labia minora lodge in the interior wall 9 of the cup. The upper face of the strip is pressed against the inner face of the labia majora. The remaining pair of support arms and straps are then connected at one of several positions

sufficient to maintain a positive tension urging the inner face of the strip portion against the inner face of the labia majora so that a fluid tight seal is maintained at all times.

CLAIMS

1. A female urinary incontinence device comprising a flexible elastic strip having an upper face and a lower face, an opening being provided in the strip communicating between the upper and lower faces, a fluid collection means surrounding the opening in a fluid tight manner on the lower face of the strip, wherein the strip and opening are sized and shaped such that when it is stretch fitted over the external urogenital organs the labia minor extends through the opening and a fluid tight fit between the upper face of the strip and the inner surface of the labia majora and around the base of the labia minora is formed, such that in use urine is conveyed from the urethra, through the labia minora, into the collection means without leakage.
2. A device according to claim 1 wherein the fluid collection device comprises a funnel portion the curved wall of which at an upper end extends circumferentially from the surface of the oval region around the opening and curves inwards to a lower open end suitable for communicating with a collection vessel,
- 3 A device according to claim 2 wherein the anterior surface of the wall of said funnel curves more sharply than the posterior surface, such that the narrow opening at the base of the funnel lies in a more horizontal plane than that of the opening in the strip.

4. A device according to claim 1 wherein said funnel has a double-walled structure, the inner curved wall narrowing symmetrically and more sharply than the outer wall so that an internal opening is formed substantially parallel to and of smaller radius than the opening in the strip.
5. A device according to claim 3 wherein a recess is formed between the posterior surface of the inner wall and the posterior surface of the outer wall such that, when the user is in a horizontal position, urine which has passed through the internal opening of the funnel is prevented from flowing back into the cavity between said opening and the oval opening of the strip.
6. A device according to any of claims wherein the exterior wall of the funnel is constructed of resilient flexible material and the interior wall is constructed with substantially the same elastic material as the strip.
7. A device according to any of claims wherein the funnel is integral to the strip.
8. A device according to any of claims 1 to 7 wherein said strip comprises divergent elongated straps at each end suitable for attachment to a supporting waistband, so that in use the strip is stretched tightly over the external urogenital organs.
9. A device according to claim 7 wherein the length of said straps is adjustable with respect to the waistband to allow for differences in size and shape of the user.

10 A device according to any preceding claim in which the strip portion is maintained under tension to press against the labia majora.

11. A urinary incontinence device further comprising a waistband and means for attachment to the device of any of claims 1 to 10.

12. A urinary incontinence device according claim 11 wherein the attachment means is adjustable to maintain a positive tension of the device against the labia majora when in use.

13 A urinary incontinence device substantially as hereinbefore described with reference to the accompanying drawings.

ABSTRACT

URINARY INCONTINENCE DEVICE

The invention relates to an external female incontinence device. The device comprises a flexible elastic strip having an opening in the strip, a fluid collection means surrounding the opening on one face, the strip and opening are sized and shaped so that when stretch fitted over the external urogenital organs the labia minor extends through the opening and a fluid tight fit between the upper face of the strip and the inner surface of the labia majora and around the base of the labia minora is formed. The device may further comprise a waistband for attachment of the device and to assist in maintaining a positive tension to press the device against the labia majora.

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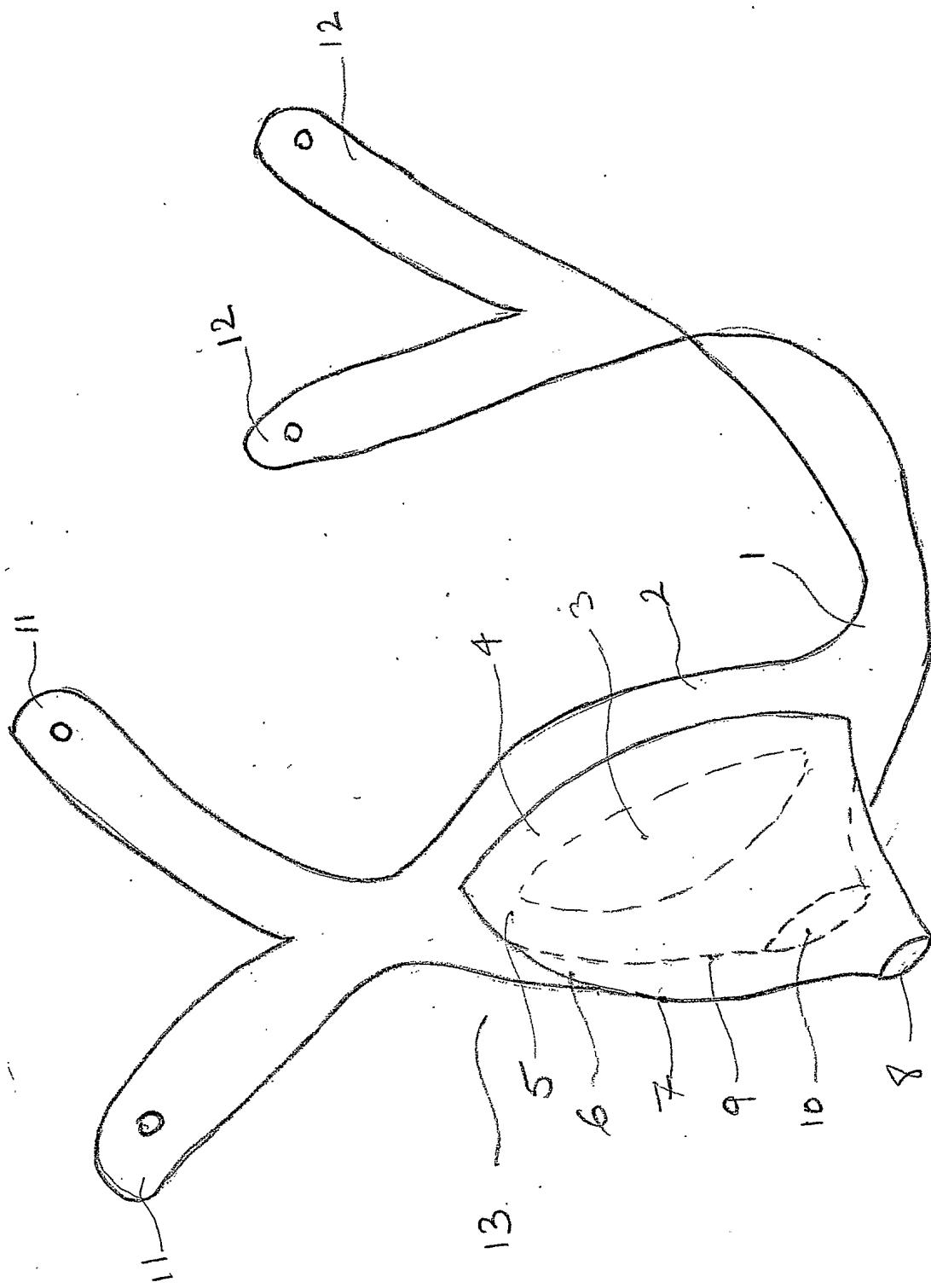


Fig 1



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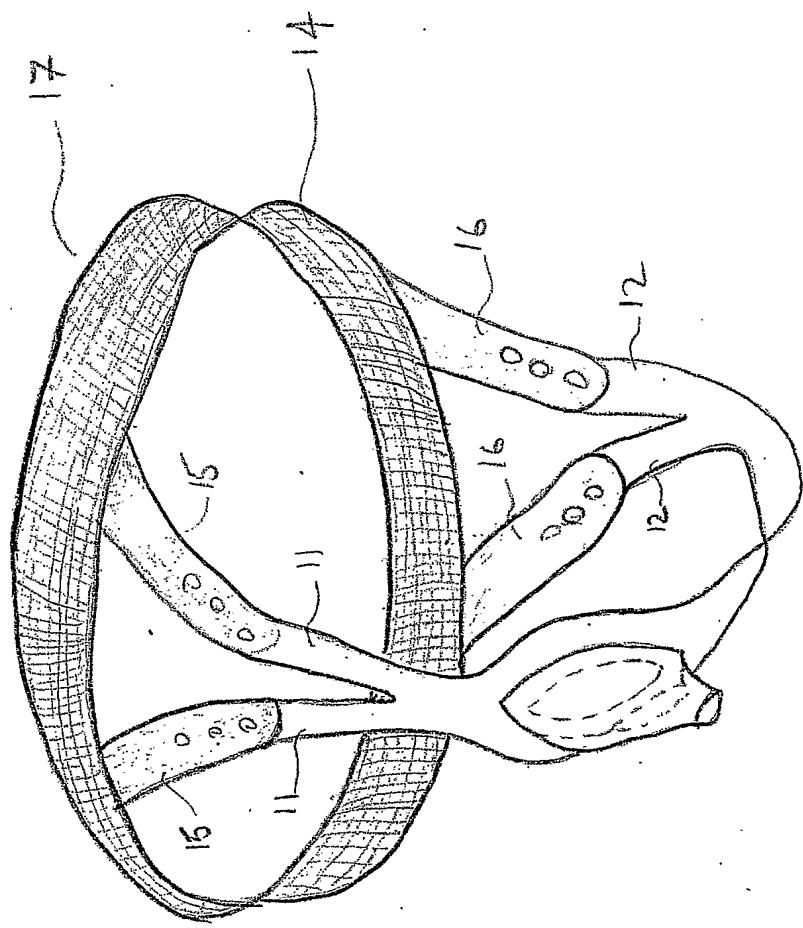


Fig 2

